K090504

Toshiba America Medical Systems, Inc.
Premarket Notification Body Organ Perfusion System, CSBP-001A

## Section 5. 510(k) Summary

MAR 5 2009

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| **Date:** | February 18, 2009 |
| **Manufacturer:** | Toshiba Medical Systems Corporation<br>1385 Shimoishigami, Otawara-shi,<br>Tochigi-ken, 324-8550, Japan |
| **Initial Importer/Distributor:**<br>**Address:** | Toshiba America Medical Systems, Inc.<br>P.O. Box 2068, 2441 Michelle Drive,<br>Tustin, CA 92781-2068 |
| **Contact:** | Paul Biggins, Director Regulatory Affairs<br>(714)730-5000 |
| **Establishment Registration Number:** | 2020563 |
| **Device Proprietary Name:** | CSBP-001A; Body Perfusion System |
| **Common Name:** | Scanner, Computed Tomography, X-Ray |
| **Classification:** | 90-JAK |
| **Regulatory Class:** | II (per 21 CFR 892.1750) |
| **Performance Standard:** | None |
| **Predicate Device(s):** | General Electric CT Perfusion 4 (k052839<br>Siemens syngo Perfusion (k073373) |
| **Reason For Submission** | New software device |

**Description of this Device:**
The CSBP-001A is a noninvasive post-processing software that runs on a PC based console of the host CT device. It has been designed to assess dynamic (time lapsed collections) CT volume scans and provide data related to the volume sets.

**Summary of Intended Uses:**
The Body Perfusion System software package is a noninvasive post-processing package that has been designed to evaluate perfusion of organs and tumors. The software can calculate blood flow, blood volume and permeability from sets of images reconstructed from dynamic CT data acquired after the injection of contrast media. The software also allows the separate calculation of the arterial and portal venous component of hepatic

perfusion. It supports evaluation of regions of interest and the visual inspection of time density curves.

When used by a qualified physician a potential application is to differentiate blood flow between normal and diseased tissue. Determination of the change of perfusion parameters during the course of treatment may be helpful in therapy monitoring.

It should be used by a trained and qualified physician.

**Safety and Effectiveness Concerns:**
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. Additionally, risk management is employed through hazard analysis which identifies potential hazards. These hazards are mitigated through labeling and software development.

**Substantial Equivalence:**
This device is substantially equivalent to the predicate devices which are commercially available at this time.

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| GE CT Perfusion 4 | k052839 | March 10, 2006 |
| Siemens syngo Volume Perfusion CT Body | k073373 | December 18, 2007 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2009

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K090504
Trade/Device Name: Body Perfusion System, CSBP-001A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 25, 2009
Received: February 26, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | (240) 276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | (240) 276-0115 |
| 21 CFR 892.xxx | (Radiology) | (240) 276-0120 |
| Other | | (240) 276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K090504

Device Name: Body Perfusion System, CSBP-001A

Indications for Use:

The Body Perfusion System software package is a noninvasive post-processing package that has been designed to evaluate perfusion of organs and tumors. The software can calculate blood flow, blood volume and permeability from sets of images reconstructed from dynamic CT data acquired after the injection of contrast media. The software also allows the separate calculation of the arterial and portal venous component of hepatic perfusion. It supports evaluation of regions of interest and the visual inspection of time density curves.

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It should be used by a trained and qualified physician.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090504